JAN 11 2002

K014117

VII. SPECIAL 510(K) SUMMARY

A. Sponsor/Submitter:

Perclose, An Abbott Laboratories Company
400 Saginaw Drive
Redwood City, CA 94063
Tel: (650) 474-3000
Fax: (650) 474-3020

B. Contact Person:

Sevrina Ciucci
Regulatory Affairs Coordinator
(650) 474-3164

C. Date of Submission: December 12, 2001

D. Trade (Brand) Name: Outback™ Catheter

E. Common Name: Percutaneous Catheter

F. Classification: Class II

G. Classification Name: Percutaneous Catheter, 21 CFR Part 870.1250

H. Product Code: 74DQY

I. Predicate Device: Outback™ Catheter (K001577)

J. Intended Use:

The Outback Catheter is intended to facilitate placement and positioning of catheters within the peripheral vasculature. The Outback Catheter is not intended for use in the coronary or cerebral vasculature.

K. Device Description:

The Outback catheter features a 6 Fr. steel-braided polyimide and polyurethane shaft through which a single-lumen steel-braided polyimide guide is housed. The guide is extendable and steerable from the tip of the catheter shaft, and features a radiopaque multi-beveled guide tip allowing for visualization under fluoroscopy. A radiopaque index on the catheter shaft is oriented to the steerable guide tip. The proximal end of the Outback Catheter features a rotating hemostasis valve through which the guide is extended and retracted via a rotational handle mechanism.

L. Summary of Substantial Equivalence:

Perclose has submitted information on indication for use, design and principle of operation, biocompatibility and performance characteristics to establish that the Outback Catheter is equivalent to currently marketed predicate device.

The Outback Catheter has the same intended use and technological characteristics as the predicate device (K001577). Results of scientific testing have ensured that all materials are biocompatible, no new adverse effects were introduced and physical properties are appropriate for the intended use.

In conclusion, the Outback Catheter has been shown to be equivalent to the Class II predicate, the previous generation Outback Catheter, on which the device is based.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2002

Ms. Sevrina Ciucci
Regulatory Affairs
Perclose, An Abbott Laboratories Company
400 Saginaw Drive
Redwood City, CA 94063

Re: K014117
Trade Name: Outback™ Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: December 12, 2001
Received: December 14, 2001

Dear Ms. Ciucci:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

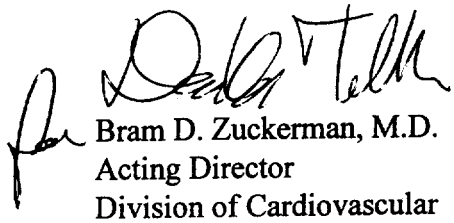
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

V. INDICATIONS FOR USE STATEMENT

Special 510(k) Number: K014117

Device Name: Outback™ 0.035" Catheter

Indications for Use: The Outback Catheter is intended to facilitate placement and positioning of catheters within the peripheral vasculature. The Outback Catheter is not intended for use in the coronary or cerebral vasculature.

There is no change to the Indications for Use.

Prescription Use ✓
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K014117